

CASWELL FILE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEW
EPA SERIES 361

PC 057501

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCESMEMORANDUM

SUBJECT: Parathion, Mutagenicity Studies

TO: Dennis Edwards PM-12
Registration Division (TS-767)FROM: Robert P. Bendzian PhD
Senior Pharmacologist
Toxicology Branch
HED (TS-769)THROUGH: William Burnam
Deputy Chief
Toxicology BranchWLB
7/26/88

Compound; Parathion

Tox Chem #637

Registration #478-3

Registrant; Chem Nova

MRID # 406447-05,06,07&08

Tox Project #8-0810

Action Requested

Review the following mutagenicity studies;

MRID 406447-05

Salmonella/mammalian-microsome plate incorporation
mutagenicity assay (Ames test) with a confirmatory assay,
T.E. Lawlor & V.O. Wagner; Microbiological Associates, Study
No. T5772.501014, 3/22/88, MRID 406447-05

MRID 406447-06

CHO/HGPRT mutation assay L.L. Yang; Microbiological
Associates, Study No. T5772.332, 3/28/88, MRID 406447-06

MRID 406447-07

Micronucleus cytogenetic assay in mice, D.L. Putman,
Microbiological Associates, Study No. T5772.122, 3/24/88,
MRID 406447-07

MRID 406447-08

Unscheduled DNA synthesis in rat primary hepatocytes,
R.D. Curren, Microbiological Associates, Study No. T5772.01,
3/28/88, MRID 406447-08

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Conclusions

MRID 406447-05 Acceptable

Parathion was not active in the reverse bacterial mutation (Ames) test with S typhimurium (Strains TA98, TA100, TA1535, TA1537 and TA1538) with or without metabolic activation at doses up to 10,000 ug per plate.

MRID 406447-06 Acceptable

Parathion was equivocally active in the CHO/HGPRT, forward gene mutation assay with or without metabolic activation when tested at doses from 0.03 to 0.3 ul/ml. Results were not dose-related and require a repeat study for verification.

MRID 406447-07 Acceptable

Parathion did not induce micronucleated polychromatic erythrocytes in male or female CD-1 mice at IP doses of 3, 13 or 26 mg/kg.

MRID 406447-08 Acceptable

Parathion did not produce evidence of unscheduled DNA synthesis at doses of 0.0001, 0.0003, 0.0006, 0.001 and 0.003 ul/ml in the rat primary hepatocyte.

Recommendation

Study -06, in the Chinese Hamster Ovary cell, produced positive results in a nondose-related manner which require verification with a repeat study. The compound was reported to be insoluble in all doses except the lowest, 0.03 ul/ml, which dose produced an apparent positive effect. The study should be performed utilizing several doses, 0.03 ul/ml and lower, to determine if a dose-related effect can be obtained.

Attachments

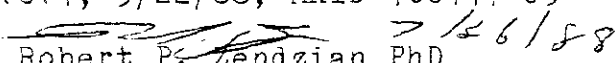
DERs

One-liner

Data Evaluation Report

Chemical Parathion (ethyl parathion)Citation

Salmonella/mammalian-microsome plate incorporation mutagenicity assay (Ames test) with a confirmatory assay, T.E. Lawlor & V.O. Wagner; Microbiological Associates, Study No. T5772.501014, 3/22/88, MRID 406447-05

Reviewed by  3/26/88
Robert P. Zendzian PhD
Senior Pharmacologist

Core Classification AcceptableConclusion

Parathion was not active in the Ames test with S. typhimurium (Strains TA98, TA100, TA1535, TA1537 and TA1538) with or without metabolic activation at doses up to 10,000 ug per plate.

Materials

Ethyl parathion (parathion) (97/98 % Technical)
Lot No. 70818-01
Receipt date 11/02/87
MBA test article ID, T5772

Positive controls

9-aminoacridine 98%
2-aminoanthracene practical grade
sodium azide practical grade

S. typhimurium (Strains TA98, TA100, TA1535, TA1537 and TA1538)

Experimental design

1. Dose range finding study

Doses of parathion from 10 to 10,000 ug per plate, with and without metabolic activation were tested against TA100.

2. Test

Parathion was tested at doses of 667, 1000, 3333, 6667 and 10,000 ug per plate with and without metabolic activation against each of the following S. typhimurium (Strains TA98, TA100, TA1535, TA1537 and TA1538). Test was performed twice with three plates per dose. Vehicle controls were included in each test. Positive controls were as follows;

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Strain	Activation	Positive Controls	Conc per plate
TA98	+	2-aminoanthracene	2.0 ug
TA98	-	2-nitrofluorene	3.0 ug
TA100	+	2-aminoanthracene	2.0 ug
TA100	-	sodium azide	1.0 ug
TA1535	+	2-aminoanthracene	2.0 ug
TA1535	-	sodium azide	1.0 ug
TA1537	+	2-aminoanthracene	2.0 ug
TA1537	-	9-aminoacridine	75 ug
TA1538	+	2-aminoanthracene	2.0 ug
TA1538	-	2-nitrofluorene	3.0 ug

Results

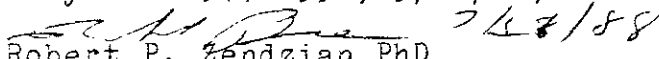
No toxicity was produced at concentrations of parathion up to 10,000 ug/plate.

No treatment-related increase in revertent colonies due to test article was observed with any of the strains tested with or without metabolic activation. Positive controls performed as expected.

Data Evaluation Report

Chemical Parathion (ethyl parathion)Citation

CHO/HGPRT mutation assay L.L. Yang; Microbiological Associates, Study No. T5772.332, 3/28/88, MRID 406447-06

Reviewed by  3/28/88
Robert P. Zendzian PhD
Senior PharmacologistCore Classification AcceptableConclusion

Parathion was equivocally active in the CHO/HGPRT forward gene mutation assay with or without metabolic activation at doses from 0.03 to 0.3 ul/ml. Results were not dose-related, positive only at 0.03 ul/ml (LDT), and require a repeat study for verification.

Materials

Test compound
Ethyl parathion (parathion) (97/98 % Technical)
Amber liquid
Lot No. 70818-01
Receipt date 11/02/87
MBA test article ID, T5772

Positive controls
ethyl methanesulfonate (EMS) lot A11H, Eastman Kodak
Benzo(a)pyrene (BaP) lot 57F-3434, Sigma

CHO-K₁-BH₄ cells (Dr. Abraham Hsie, Oak Ridge National Laboratories)

Experimental design

1. Dose range finding study

Doses of parathion from 0.0001 to 10 ul/ml with and without metabolic activation were tested.

2. Test

Parathion was tested at doses of 0.03, 0.06, 0.1, 0.2 and 0.3 ul/ml with and without activation. Untreated and solvent controls were run with and without activation. EMS was the unactivated positive control at 0.2 ug/ml and BaP the activated positive control at 4 ug/ml. Three plates were used for each treatment.

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Results

1. Toxicity test

No consistent decreases in cloning efficiency, compared to solvent control, were seen in either preliminary or concurrent toxicity tests.

2 Mutation assay

Parathion produced equivocal results in both the unactivated and activated test (tables 3 and 4 from the report).

Cloning efficiency was not affected by treatment in the unactivated test but was depressed slightly by all treatments in the activated test.

In the unactivated test, the number of mutants/ 10^6 cells was 3.5 in the solvent control, 133.3 for the positive control and 88.7, 9.5, 19.0, 1.0 and 24.3 for doses of 0.03, 0.06, 0.1, 0.2 and 0.3 ul/ml of parathion respectively.

In the activated test, the number of mutants/ 10^6 cells was 3.4 in the solvent control, 307.1 for the positive control and 53.3, 1.1, <1.0, 4.6 and <1.2 for doses of 0.03, 0.06, 0.1, 0.2 and 0.3 ul/ml of parathion respectively.

Test compound was reported to be insoluble at concentrations of 0.06 ul/ml and higher. Since the test compound was only soluble at the lowest dose, which appeared to produce a positive result, the study must be repeated at 0.03 ul/ml and several lower doses to test for a dose-related effect.

study No. 15772.332

TABLE 2

CHO/HGPRT MUTATION ASSAY
Concurrent Toxicity Test

-S-9				+S-9			
Treatment ¹	Colonies/ Plate ⁴	Cloning Efficiency ²	Relative Cloning Efficiency ³ (%)	Treatment ¹	Colonies/ Plate ⁴	Cloning Efficiency ²	Relative Cloning Efficiency ³ (%)
Untreated	90			Untreated	120		
Control	91			Control	109		
	99	0.93	96		106	1.12	87
Solvent	98			Solvent	127		
(DMSO)	96				136		
	96	0.97	100		124	1.29	100
Ethyl Parathion (97/98% Technical)				Ethyl Parathion (97/98% Technical)			
0.3 ul/ml	130			0.3 ul/ml	111		
	99				127		
	119	1.16	120		90	1.09	85
0.2 ul/ml	83			0.2 ul/ml	105		
	89				94		
	88	0.87	90		103	1.01	78
0.1 ul/ml	118			0.1 ul/ml	100		
	112				99		
	117	1.16	120		116	1.05	81
0.06 ul/ml	90			0.06 ul/ml	101		
	99				94		
	90	0.93	96		101	0.99	77
0.03 ul/ml	104			0.03 ul/ml	119		
	103				121		
	96	1.01	104		99	1.13	88
EMS	101			BaP	44		
	103				49		
	125	1.10	113		51	0.48	37

¹ Cells were exposed to the test article in the absence (- S-9) or presence (+ S-9) of an exogenous metabolic activation for 5 hours at 37±1°C.

² Cloning efficiency = $\frac{\text{total colonies counted}}{100 \text{ cells} \times \text{number replicates}}$

³ Relative Cloning Efficiency = $\frac{\text{cloning efficiency of treatment group} \times 100}{\text{cloning efficiency of solvent group}}$

Study No. T5772.332

TABLE 3

CHO/HGPRT MUTATION ASSAY

NON-ACTIVATED STUDY

Treatment ¹	Cloning Efficiency at Selection					Mutant Colonies/Selection Dish					Total Mutant Colonies	Mutants/10 ⁶ Clonable Cells ³
	Colonies per Dish			Total Colonies	Cloning Efficiency ²							
	1	2	3			1	2	3	4	5		
Untreated Control	85	89	84	258	0.86	1	5	4	5	2	17	19.8
Solvent (DMSO)	108	98	136	342	1.14	1	0	0	2	1	4	3.5
Ethyl Parathion (97/98% Technical)												
0.3 ul/ml	116	99	106	321	1.07	8	4	4	8	2	26	24.3
0.2 ul/ml	90	98	101	289	0.96	1	0	0	0	0	1	1.0
0.1 ul/ml	99	98	102	299	1.00	8	1	3	2	5	19	19.0
0.06 ul/ml	78	88	85	251	0.84	3	1	1	1	2	8	9.5
0.03 ul/ml	105	111	128	344	1.15	22	26	13	21	20	102	88.7
EMS	116	117	112	345	1.15	38	29	28	32	27	154	133.9

¹ Cells were exposed to the test article for 5 hours at 37±1°C.² Cloning efficiency = $\frac{\text{Total Colonies Counted}}{\text{Dishes Counted} \times 100 \text{ cells/dish}}$ ³ Mutants/10⁶ clonable cells = $\frac{\text{Total Mutant Colonies}}{\text{Number Selection dishes} \times \text{Cloning Efficiency} \times 2 \times 10^5 \text{ cells}} \times 10^6$

Study No. 15772.332

TABLE 4
CHO/HGPRT MUTATION ASSAY

ACTIVATED STUDY

Treatment ¹	Cloning Efficiency at Selection					Mutant Colonies/Selection Dish					Total Mutant Colonies	Mutants/10 ⁶ Clonable Cells ³
	Colonies per Dish			Total Colonies	Cloning Efficiency ²	1	2	3	4	5		
Untreated Control	95	85	94	274	0.91	2	5	4	3	4	18	19.8
Solvent (DMSO)	75	92	95	262	0.87	0	0	0	2	1	3	3.4
Ethyl Parathion (97/98% Technical)												
0.3 ul/ml	70	91	82	243	0.81	0	0	0	0	0	0	< 1.2 ⁴
0.2 ul/ml	69	67	60	196	0.65	2	0	1	0	0	3	4.6
0.1 ul/ml	102	91	102	295	0.98	0	0	0	0	0	0	< 1.0 ⁴
0.06 ul/ml	106	86	90	282	0.94	0	0	0	1	0	1	1.1
0.03 ul/ml	81	96	93	270	0.90	3	10	19	8	8	48	53.3
BaP	82	85	86	253	0.84	47	65	43	48	55	258	307.1

¹ Cells were exposed to the test article in the presence of an S-9 reaction mixture for 5 hours at 37±1°C.

² Cloning efficiency = $\frac{\text{Total Colonies Counted}}{\text{Dishes Counted} \times 100 \text{ Cells/dish}}$


³ Mutants/10⁶ clonable cells = $\frac{\text{Total Mutant Colonies}}{\text{Number Selection dishes} \times \text{Cloning Efficiency} \times 2 \times 10^5 \text{ cells}} \times 10^6$

⁴ Calculated on the basis of <1 mutant colony observed in a total of 5 dishes.

Data Evaluation Report

Chemical Parathion (ethyl parathion)Citation

Micronucleus cytogenetic assay in mice, D.L. Putman, Microbiological Associates, Study No. T5772.122, 3/24/88, MRID 406447-07

Reviewed by  7/26/88
Robert P. Zendzian PhD
Senior Pharmacologist

Core Classification Acceptable

Conclusion

Parathion did not induce micronucleated polychromatic erythrocytes in male or female CD-1 mice at IP doses of 3, 13 or 26 mg/kg.

Materials

Test compound
Ethyl parathion (parathion) (97/98 % Technical)
Clear tan liquid
Lot No. 70818-01
Receipt date 11/02/87
MBA test article ID, T5772

Positive control
Triethylenemelamine, (TEM) Lot 45272

CD-1 mice, Charles River Breeding Laboratories

Experimental design and Results

1. Toxicity study

Doses of parathion from 10 to 65 mg/kg were administered by the IP route to groups of 5 male and 5 female mice. Detailed design and results are presented in Table 1 from the report. Lethality was observed at doses of 40 mg/kg and higher.

2. Test

Parathion was tested at doses of 3, 13 and 26 mg/kg by the IP route to groups of 15 male and 15 female mice. TEM, the positive control, was administered, by the IP route, at a dose of 0.25 mg/kg to 5 male and 5 female mice. Detailed design and results are presented in Table 2 from the report. No compound-related effects on the number of micronucleated polychromatic erythrocytes were observed. The positive control was active.

TABLE 1

TOXICITY STUDY WITH ETHYL PARATHION (97/98% TECHNICAL) IN CD-1 MICE

TREATMENT	SEX	GROUP MEAN BODY WEIGHTS (gms)			% CHANGE ¹		MORTALITY ²
		PRETREATMENT	DAY 1	DAY 3	DAY 1	DAY 3	
Corn Oil 10 ml/kg	M	34.1 ± 1.4	34.0 ± 1.3	34.5 ± 1.8	-0.3%	1.2%	0 / 5
	F	23.9 ± 2.1	23.7 ± 2.0	23.9 ± 1.9	-0.8%	0.0%	0 / 5
Ethyl Parathion 65 mg/kg	M	32.4 ± 2.7					5 / 5
	F	24.5 ± 1.2					5 / 5
56 mg/kg	M	33.3 ± 1.0					5 / 5
	F	26.4 ± 0.7					5 / 5
48 mg/kg	M	34.5 ± 1.1	29.6	24.9	-14.2%	-27.8%	5 / 5
	F	25.5 ± 0.4	24.9 ± 0.4	25.4 ± 0.4	-2.4%	-0.4%	3 / 5
40 mg/kg	M	33.1 ± 1.6	27.8 ± 1.4	29.9 ± 3.7	-16.0%	-9.7%	3 / 5
	F	24.0 ± 1.7	22.1 ± 2.0	22.8 ± 2.1	-7.9%	-5.0%	0 / 5
25 mg/kg	M	32.1 ± 1.0	31.1 ± 1.4	32.5 ± 1.0	-3.1%	1.2%	0 / 5
	F	23.9 ± 1.6	23.2 ± 1.8	23.4 ± 1.4	-2.9%	-2.1%	0 / 5
15 mg/kg	M	33.9 ± 2.4	33.3 ± 2.1	34.0 ± 2.1	-1.8%	0.3%	0 / 5
	F	24.6 ± 2.1	24.5 ± 1.7	24.4 ± 1.7	-0.4%	-0.8%	0 / 5
10 mg/kg	M	34.7 ± 1.5	34.7 ± 2.0	35.8 ± 2.0	0.0%	3.2%	0 / 5
	F	24.7 ± 1.1	24.2 ± 1.1	24.8 ± 1.0	-2.0%	0.4%	0 / 5

¹% Change = (Post-treatment weight - Pretreatment weight) x 100

Pretreatment weight

²Reported as number of animals dead 7 days after dose administration/total number tested.

TABLE 2

MICRONUCLEATED POLYCHROMATIC ERYTHROCYTES IN BONE MARROW: SUMMARY

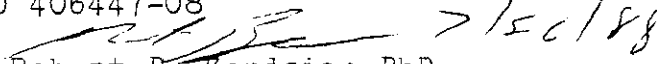
TREATMENT	SEX	TIME (HR)	NUMBER OF MICE	PCE/TOTAL ERYTHROCYTES	MICRONUCLEATED POLYCHROMATIC ERYTHROCYTES	
					NUMBER PER 1000 PCE'S (MEAN \pm S.D.)	NUMBER PER PCE'S SCORED
Corn oil						
10 ml/kg	M	24	5	0.45	1.8 \pm 1.48	9 / 5000
		48	5	0.50	1.6 \pm 1.52	8 / 5000
		72	5	0.45	2.0 \pm 1.00	10 / 5000
	F	24	5	0.47	1.2 \pm 0.84	6 / 5000
		48	5	0.62	1.2 \pm 1.64	6 / 5000
		72	5	0.54	2.0 \pm 0.71	10 / 5000
Ethyl Parathion (97/98% Technical)						
26 mg/kg	M	24	4	0.52	2.8 \pm 0.50	11 / 4000
		48	0 ²			
		72	0 ²			
	F	24	5	0.56	1.0 \pm 0.71	5 / 5000
		48	0 ²			
		72	0 ²			
13 mg/kg	M	24	4	0.47	0.8 \pm 0.96	3 / 4000
		48	5	0.47	1.2 \pm 1.30	6 / 5000
		72	5	0.46	1.8 \pm 1.48	9 / 5000
	F	24	5	0.55	2.4 \pm 0.89	12 / 5000
		48	5	0.49	0.6 \pm 0.89	3 / 5000
		72	5	0.57	2.6 \pm 2.61	13 / 5000
3 mg/kg	M	24	5	0.49	1.6 \pm 1.34	8 / 5000
		48	5	0.50	0.6 \pm 0.55	3 / 5000
		72	5	0.57	1.0 \pm 0.71	5 / 5000
	F	24	5	0.54	0.4 \pm 0.55	2 / 5000
		48	5	0.49	1.4 \pm 1.67	7 / 5000
		72	5	0.59	0.6 \pm 0.55	3 / 5000
TEM						
0.25 mg/kg	M	24	5	0.41	45.8 \pm 10.43	229 / 5000*
	F	24	5	0.48	34.0 \pm 14.54	170 / 5000*

1*, $p \leq 0.05$ (Kastenbaum-Bowman Tables)²Mice died prior to scheduled sacrifice

Data Evaluation Report

Chemical Parathion (ethyl parathion)Citation

Unscheduled DNA synthesis in rat primary hepatocytes,
R.D. Curren, Microbiological Associates, Study No. T5772.01,
3/28/88, MRID 406447-08

Reviewed by  7/5/88
Robert P. Zendzian PhD
Senior Pharmacologist

Core Classification AcceptableConclusion

Parathion did not produce evidence of unscheduled DNA synthesis at doses of 0.0001, 0.0003, 0.0006, 0.001 and 0.003 ul/ml in the rat primary hepatocyte.

Materials

Test compound
Ethyl parathion (parathion) (97/98 % Technical)
Amber liquid
Lot No. 70818-01
Receipt date 11/02/87
MBA test article ID, T5772

Positive control
7.12-dimethylbenz(a)anthracene (DMBE) Kodak lot A15A

Adult male Sprague-Dawley rats from Charles River

Experimental design and results

1. Cytotoxicity test.

Ten doses, two replicates, of parathion from 0.0003 to 10 ul/ml were tested in the preliminary cytotoxic assay. Nine doses, three replicates, of parathion from 0.00003 to 0.03 ul/ml were tested in the parallel cytotoxic assay. Table 2, from the report presents the results of the parallel assay. Parathion was cytotoxic at doses of 0.006 ul/ml and higher.

2. Unscheduled DNA test

Eight doses, three replicates, of parathion from 0.0001 to 0.03 ul/ml were tested in the unscheduled DNA test. The positive control, DMBA, was tested at 3.0 and 5.0 ug/ml. Solvent (DMSO 10 ul/ml) and media controls were also tested. Table 3, from the report presents the results of the test. Test compound was not active at doses up to 0.003 ul/ml, higher doses were too toxic to evaluate. Positive control was active at 3.0 and 5.0 ug/ml.

Study No. T5772.380

TABLE 2

PARALLEL CYTOTOXICITY ASSAY
LDH RELEASE
UNSCHEDULED DNA SYNTHESIS

TREATMENT	DISHES COUNTED	LDH*	AVERAGE LDH*	CORRECTED LDH*	RELATIVE TOXICITY	TREATMENT	DISHES COUNTED	LDH*	AVERAGE LDH*	CORRECTED LDH*	RELATIVE TOXICITY
Ethyl Parathion (97/98% Technical)						DMBA					
0.03 ul/ml	3	252				5.0 ug/ml	3	148			
		265	270.0	160.7	74%			147	152.7	43.3	20%
		293						163			
0.01 ul/ml	3	307				3.0 ug/ml	3	130			
		220	246.3	137.0	63%			120	122.3	13.0	6%
		212						117			
0.006 ul/ml	3	255				DMSO (Solvent Control for DMBA and Test Article)					
		254	242.7	133.3	62%	10 ul/ml	3	119			
		219						106	109.3	0.0	0%
				103							
0.003 ul/ml	3	97				WME (Media Control)					
		97	107.0	-2.3	-1%		3	102			
		127						126	115.7	6.3	3%
				119							
0.001 ul/ml	3	95				DMSO					
		104	102.3	-7.0	-3%	10 ul/ml	3	368			
		108						293	326.0	216.7	100%
				317							
0.0006 ul/ml	3	115				Ethyl Parathion (97/98% Technical)					
		98	102.0	-7.3	-3%	0.03 ul/ml	3	275			
		93						306	282.7	173.3	80%
				267							
0.0003 ul/ml	3	93									
		91	99.3	-10.0	-5%						
		114									
0.0001 ul/ml	3	132									
		106	117.0	7.7	4%						
		113									
0.0003 ul/ml	3	110									
		110	113.0	3.7	2%						
		119									

* CORRECTED LDH = AVERAGE LDH - SOLVENT CONTROL LDH

** LDH CONTROL = THE AMOUNT OF CORRECTED LDH ACTIVITY RELEASED BY EXPOSURE OF CONTROL CELLS TO 1% TRITON (100% LYSIS).

*** RELATIVE TOXICITY = CORRECTED LDH / 100% LDH CONTROL

LDH MEASURED IN INTERNATIONAL UNITS PER LITER

Study No. T5772.380

TABLE 3

SUMMARY OF UDS ASSAY
WITH ETHYL PARATHION (97/98% TECHNICAL)

TREATMENT	RELATIVE SURVIVAL	SLIDE DESIGNATION	NO. OF NUCLEI COUNTED	AVERAGE NET GRAINS PER NUCLEUS			S.D.	GRAND MEAN	S.D.	PERCENT CELLS WITH 5 OR MORE NET NUCLEAR GRAINS
Ethyl Parathion (97/98% Technical)										
0.03 ul/ml	26%			Too Toxic to be Evaluated for UDS						
0.01 ul/ml	37%			Too Toxic to be Evaluated for UDS						
0.006 ul/ml	38%			Too Toxic to be Evaluated for UDS						
0.003 ul/ml	101%	23A	50	-2.4	+/-	3.6	-2.3	+/-	3.7	3%
		23A & 23B	50	-1.9	+/-	3.8				
		23C	50	-2.7	+/-	3.7				
0.001 ul/ml	103%	21A	50	-0.8	+/-	3.4	-2.3	+/-	3.6	2%
		21B	50	-2.0	+/-	3.1				
		21C	50	-4.2	+/-	3.6				
0.0006 ul/ml	103%	28A	50	-1.8	+/-	3.2	-1.5	+/-	3.0	1%
		28A	50	-0.7	+/-	3.0				
		28C	50	-2.0	+/-	2.8				
0.0003 ul/ml	105%	26A	50	-3.0	+/-	2.6	-2.2	+/-	3.1	3%
		26B	50	-2.4	+/-	3.2				
		26C	50	-1.1	+/-	3.2				
0.0001 ul/ml	96%	24A	50	-2.6	+/-	3.2	-2.2	+/-	2.9	1%
		24B	50	-1.7	+/-	2.6				
		24C	50	-2.2	+/-	3.0				
DMBA										
5.0 ug/ml	80%	53A	28 ¹	5.8	+/-	3.8	6.9*	+/-	3.8	70%
		53C	28 ¹	7.9	+/-	3.5				
3.0 ug/ml	94%	55A	50	7.5	+/-	3.9	6.8*	+/-	4.6	66%
		55B	50	6.5	+/-	5.4				
		55C	50	6.3	+/-	4.3				
DMSO (Solvent Control for DMBA)										
10 ul/ml	100%	52A	50	-0.9	+/-	1.6	-1.6	+/-	2.0	0%
		52B	50	-1.9	+/-	2.2				
		52C	50	-1.9	+/-	2.0				
WME (Media Control)										
	97%	51A	50	-0.9	+/-	3.2	-1.3	+/-	2.7	3%
		51B	50	-2.1	+/-	3.0				
		51C	50	-1.0	+/-	1.7				

S.D. Standard Deviation

* Significant (See Protocol: Section 8.0, Evaluation of Test Results)

¹ Due to excessive toxicity less than 50 nuclei per slide could be evaluated for UDS



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